DETAILED ACTION

1. Applicant's election of Group I: Claims 7 and 15 and claims 1-6, 8-14, 16-21 reading on R^6, R^7 and R^8 are H or alkyl in the reply filed on Sep. 24, 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The requirement is still deemed proper and is therefore made FINAL.

Claims 7, 15 and claims 1-6, 8-14, 16-21 reading on R^6, R^7 and R^8 are H or alkyl are prosecuted. Claims 22-23 and the remaining subject matter of claims 1-6, 8-14, 16-21 reading on R^6, R^7 and R^8 are not H or alkyl are withdrawn from consideration per 37 CFR 1.142(b)

2. Claims 19-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what does the term "medicament" mean. Is it a composition containing a therapeutically effective amount of a medicine? Or is it administration of a medicine to cause an effect in treating one of the disorders? The claims are considered hybrid claims containing multiple categories of invention i.e. both composition and method of use. The claims are confusing and indefinite as explained:

If the claims are drawn to pharmaceutical composition, how many are there? Please note that treatment of disease or disorder in current practice is pathology or symptom oriented. The effective process/compositiion of treating obesity would require decrease of food intake. Such a process/composition would be detrimental to the person who is anorexic or bulimic. In addition, for a composition to be effective in treating diabetes, a process/effective amount of lowing blood glucose (please note that treating diabetes or diabetic complication are different disorders) is needed; for treating cardiovascular disorder such as ischemic coronary disorder, an coronary vasodilating process/effective amount is needed; for treating epilepsy, an anticonvulsive process/effective amount is needed, etc. Therefore, it is unclear how many compositions or processes are encompassed by the claims. In addition, the claimed processes or

compositions are intended for accomplishing opposite effects such as treating obesity and bulimia at the same time which is incredible.

Further more, the claims also includes "propylaxis" which is self conflicting since for example if the composition is for "improvement" or "treatment" of a diagnosed disorder, there could not be any de novo prophylaxis efficacy.

3. Claims 1-2, 5-6, 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification while provided how to make the compounds or prima facie modification such compounds to its pharmaceutically addition salt with pharmaceutically acceptable acids, does not provide enablement for making unknown solvates. It is well recognized in the art that confusion may occur even among experts in so far as what constitutes a polymorph material. Seddon clearly described that in this century, with the advancement of the chemical art, there should never be any doubt about the chemical identity of a material. Therefore, if a solvate, a hydrate or a salt is made, one should clearly identify such material with its chemical identity.

It is further recognized by artisan in the field that material having identical chemical composition i.e. structural formula, may differ in solid forms, i.e. polymorph (Yu et al. p.122) and "solvates" of a compound, if existed are different chemical identities from the non-solvated material, and the identification of solvates must be evidenced by such data as TGA loss, H1 NMR spectroscopy, Karl Fischer titration etc. (Yu et al. p.122).

In addition, skilled person in the art is well aware of that the different chemical identities which are prepared by different processes, acquiring one does not offer any operability in possession of another. Braga et al. (p.3640) explicitly provided the state of the art understanding that in possession of a compound per se would be a nightmare to predict how many or what kind of a solvate it can form. Absent of explicit enabling teaching such as what solvents, termperature, concentration etc. a process for making compound per se does not offer any enablement for any solvate.

The specification described that the "prodrug" is the modification wherein "a moiety that will give rise to a pharmacologically *active* metabolite" of a compound. Please note that the "prodrug" of the claims are structural moieties. To qualify as a prodrug modification the relationship of inactive precursor being in vivo metabolically changed into an "active" compound as described must be provided. In the specification, no description or provision of which "prodrug" modification meets such prodrug requirement nor how can they be used i.e different dosage from administering/preparing an effective pharmaceutical composition. Without any guidelines, one having ordinary skill is offered mere language rather than enablement since among the whole prodrug literature no guidelines as to which one to pick or choose as to have any predictability of operability. The law requires that the specification itself to inform not for other to find out by themselves. In re Gardner 166 USPQ 138.

As a corollary to the above 2nd paragraph rejection, claims 19-21 are also rejected under 35 USC 112 first paragraph as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As it was delineated in section 2, the claims are drawn to different "effective" dosage for the specific disorder including opposite effects as well as for *all* CNS disorder, *all* cardiovascular disorder etc. which is incredible. For the time being there has not been evidenced that a single drug can be operable for all the disorders as claimed. In absence of any dosage information, the specification offered mere language rather than enablement.

4. Claims 1-21 are directed to the same invention as that of claim 22 of commonly assigned SN 10/565,979, especially guided by p.52 US2008/0119516 compounds 166-167 identical to compounds 5-6 of instant claim 15. The issue of priority under 35 U.S.C. 102(f) of this single invention must be resolved.

Please note that the copending application has a "different" inventive entity as the instant application.

Since the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter

2300), the assignee is required to state which entity is the prior inventor of the conflicting subject matter. A terminal disclaimer has no effect in this situation since the basis for refusing more than one patent is priority of invention under 35 U.S.C. 102(f) and not an extension of monopoly.

Failure to comply with this requirement will result in a holding of abandonment of this application.

5. Claims 1-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 22 in view of compounds 166-167 of copending Application No. 10/565,979. Although the conflicting claims are not identical, they are not patentably distinct from each other because anticipatory species encompassed by the copending claims rendered the variation of the species by the gereic teaching prima facei obviious.

The claims or the copending application included compounds 166-167 which anticipated the instant claims when one of R^1-R^4 is OR^8 and R^8 is H or alkyl.. Broadly, the generic claims or the copending application included that the OR^8 can be at other position on the phenyl ring as well as on the carbazolyl moiety (see p.62 claim 22 formula E, R^E is optionally alkoxy). Therefore, overlapping subject matter fully embraced by the copending claims are being claimed in the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting

ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Andres, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
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/Celia Chang/
Primary Examiner
Art Unit 1625